

Listing of the Claims Per 37 C.F.R. §1.121

1. (Currently amended) A cranial orthosis for preventing positional plagiocephaly in infants comprising a protective shell having an interior surface that is operable to accommodate infant head growth and conformed in shape to the surface curvature of a normal human infant cranium, thereby defining a cavity for receiving the head of an infant having compliant, developing head areas to be protected, the cavity being sized to provide a close, non-interfering fit of the conformed interior surface in facing relation to the developing head areas to be protected, whereby when an infant's head is received in the protective cavity, the infant's head weight forces are spread substantially uniformly across the conformed interior surface that engages one or more of the developing head areas while the infant is resting on a sleep surface in a supine position.

2. (Original) The cranial orthosis for preventing positional plagiocephaly in infants as set forth in claim 1, wherein the protective shell includes interior surfaces that are smoothly contoured and conformed in shape to the surface curvatures of the occipital, temporal and parietal areas, respectively, of a human infant cranium having normal size, shape and symmetry of a healthy infant of given age and gender.

3. (Original) The cranial orthosis for preventing positional plagiocephaly in infants as set forth in claim 1, wherein the cavity is slightly oversized relative to the head of an infant to be protected so that the infant's head can be turned from side-to-side on the sleep surface without imposing binding engagement of the protective shell against the soft developing areas of the infant's head.

4. (Original) The cranial orthosis for preventing positional plagiocephaly in infants as set forth in claim 1, wherein the protective shell is loosely fitted relative to the head of an infant to be protected so that the orthosis can be worn while the infant is resting in a supine position on a sleep surface substantially without imposing torque forces against the soft developing areas of the infant's head.

5. (Original) The cranial orthosis for preventing positional plagiocephaly in infants as set forth in claim 1, the protective shell including a crown portion, left and right wing portions extending bilaterally from the crown portion and rostral end portions extending from the wing portions.

6. (Original) The cranial orthosis for preventing positional plagiocephaly in infants as set forth in claim 5, wherein the wing portions are dimensioned to provide at least partial overlapping coverage over the parietal areas and the temporal areas of an infant's head when it is received in the protective shell.

7. (Original) The cranial orthosis for preventing positional plagiocephaly in infants as set forth in claim 5, wherein the rostral end portions are dimensioned to provide at least partial overlapping coverage over an infant's fronto-parietal and temporal areas when it is received in the protective shell.

8. (Original) The cranial orthosis for preventing positional plagiocephaly in infants as set forth in claim 5, wherein the crown is dimensioned to provide overlapping coverage over substantially all of the occipital area of an infant's head when it is received in the protective shell.

9. (Original) The cranial orthosis for preventing positional plagiocephaly in infants as set forth in claim 5, wherein the wing and rostral portions are dimensioned to provide limited overlapping coverage whereby the upper aspects of the parietal, temporal and frontal bones are only partially covered by the appliance in the protective position, thus allowing good air circulation and heat transfer over most of the infant's head, while preventing uneven contact of the relatively soft, compliant occipital areas against the sleep surface.

10. (Currently amended) A cranial orthosis for preventing positional plagiocephaly in infants having a relatively soft developing head area to be protected, comprising a protective headband having an interior surface that is operable to accommodate infant head growth and contoured to conform in shape to the surface curvature of a normal human infant cranium, thereby defining a pocket for receiving the head of an infant to be protected, wherein the pocket is slightly oversized relative to the head of the infant, thereby providing a close but non-interfering fit of the headband about the infant's head, the contoured interior surface being disposed in facing relation to developing head area to be protected, thereby allowing the headband to be worn while the infant is resting on a sleep surface in a supine position substantially without imposing focused torque forces on the infant's head.

11. (Original) The cranial orthosis for preventing positional plagiocephaly in infants as set forth in claim 10, the protective headband including interior surfaces that are contoured and conformed in shape to the surface curvatures of the occipital, temporal and parietal areas, respectively, of a human infant cranium having normal size, shape and symmetry of a healthy human infant of given age and gender.

12. (Original) The cranial orthosis for preventing positional plagiocephaly in infants as set forth in claim 10, wherein the pocket is slightly oversized relative to the head of an infant to be protected, thereby allowing the infant

to turn its head from side-to-side on the sleep surface without imposing focused torque forces or binding engagement of the protective headband against the infant's head.

13. (Currently amended) The cranial orthosis for preventing positional plagiocephaly in infants as set forth in claim 10, wherein the protective headband is dimensioned for a loose fit relative to the head of an infant to be protected, thereby allowing the headband to be worn while the infant is resting on a sleep surface in a supine position substantially without imposing torque forces on the infant's head, while distributing the infant's head weight forces over a large segment ~~its cranial of its~~ cranial vault.

14. (Original) The cranial orthosis for preventing positional plagiocephaly in infants as set forth in claim 10, the protective headband including a crown portion, left and right wing portions extending bilaterally from the crown portion and rostral end portions extending from the wing portions.

15. (Original) The cranial orthosis for preventing positional plagiocephaly in infants as set forth in claim 14, wherein the left and right wing portions are dimensioned to provide at least partial overlapping coverage over the parietal areas and the temporal areas when the infant's head is received in the pocket.

16. (Original) The cranial orthosis for preventing positional plagiocephaly in infants as set forth in claim 14, wherein the rostral end portions are dimensioned to provide at least partial overlapping coverage over an infant's fronto-parietal and temporal areas when the infant's head is received in the pocket.

17. (Currently amended) A cranial orthosis for preventing acquired plagiocephaly in infants comprising a helmet having an interior surface that is operable to accommodate infant head growth and contoured and conformed in shape to the surface curvature of a human infant cranium, thereby defining a cavity for receiving the head of an infant having soft developing areas to be protected, the cavity being sized to allow nesting engagement of the infant's head against the conformed interior surface, whereby when the infant's head is received in the protective cavity, the infant's head weight forces are distributed substantially uniformly across the conformed interior surface that nests against one or more of the soft developing head areas while the infant is lying on a sleep surface in the supine resting position.

18. (Original) The cranial orthosis for preventing positional plagiocephaly in infants as set forth in claim 17, the helmet including interior surfaces that are smoothly contoured and conformed in shape to the surface curvatures of the occipital, temporal and parietal areas, respectively, of a human infant cranium having normal size, shape and symmetry of a healthy infant of given age and gender.

19. (Original) The cranial orthosis for preventing positional plagiocephaly in infants as set forth in claim 17, wherein the helmet is loosely fitted relative to the developing head areas of an infant to be protected, thereby allowing the helmet to be worn while the infant is resting on a sleep surface in a supine position substantially without imposing focused torque forces on the infant's occipital region.

20. (Original) The cranial orthosis for preventing positional plagiocephaly in infants as set forth in claim 17, the helmet including a crown portion, left and right wing portions extending bilaterally from the crown portion and rostral end portions extending from the wing portions.

21. (Original) The cranial orthosis for preventing positional plagiocephaly in infants as set forth in claim 20, wherein the left and right wing portions are dimensioned to provide at least partial overlapping coverage over the parietal areas and temporal areas of the infant's head when it is received in the protective helmet.

22. (Original) The cranial orthosis for preventing positional plagiocephaly in infants as set forth in claim 20, wherein the rostral end portions are dimensioned to provide at least partial overlapping coverage over the fronto-parietal and temporal areas of an infant when the helmet is worn in the protective position.

23. (Original) The cranial orthosis for preventing positional plagiocephaly in infants as set forth in claim 17, wherein the contoured interior surface of the helmet is dimensioned to provide overlapping coverage over substantially all of the occipital area of the infant's head when the helmet is worn in the protective position.



24. (Currently amended) A cranial orthosis for preventing acquired plagiocephaly in infants having a soft developing head area to be protected, comprising a molded appliance having an interior surface that is operable to accommodate infant head growth and conformed in shape to the surface curvature of a human infant cranium, thereby defining a protective pocket for receiving an infant's head, the pocket being sized to provide a close, non-compressive fit of the conformed interior surface in facing relation to the developing head area to be protected, whereby when an infant's head is received in the protective pocket and the infant is resting on a sleep surface in a supine position, the infant's head weight forces are spread substantially uniformly across the conformed interior surface facing the developing head area.

25. (Original) The cranial orthosis for preventing positional plagiocephaly in infants as set forth in claim 24, the molded appliance including interior surfaces that are contoured and conformed in shape to the surface curvatures of the occipital, temporal and parietal arcas, respectively, of a human infant cranium having normal size, shape and symmetry of a healthy infant of given age and gender.

26. (Original) The cranial orthosis for preventing positional plagiocephaly in infants as set forth in claim 24, characterized in that the pocket is slightly oversized relative to the head of an infant to be protected, thereby allowing the

infant's head to turn from side-to-side without imposing binding engagement of the molded appliance against the developing head area.

27. (Original) The cranial orthosis for preventing positional plagiocephaly in infants as set forth in claim 24, wherein the molded appliance is loosely fitted relative to the head of an infant to be protected, whereby when an infant's head is received in the protective pocket and the infant is resting on a sleep surface in a supine position, the contoured interior surfaces provide support for the areas to be protected substantially without imposing focused torque forces on the infant's occiput.

28. (Original) The cranial orthosis for preventing positional plagiocephaly in infants as set forth in claim 24, wherein the protective cavity is sized to provide nesting engagement of the soft developing area against the conformed interior surface, whereby when the infant's head is received in the protective pocket and the infant is resting on a sleep surface in a supine position, the infant's head weight forces are distributed substantially uniformly over the conformed interior surface that engages the soft developing area.

29. (Original) The cranial orthosis for preventing positional plagiocephaly in infants as set forth in claim 24, the molded appliance including a crown portion, left and right wing portions extending bilaterally from the crown portion and rostral end portions extending from the wing portions.

30. (Original) The cranial orthosis for preventing positional plagiocephaly in infants as set forth in claim 29, wherein the left and right wing portions are dimensioned to provide at least partial overlapping coverage over the parietal areas and the temporal areas when the infant's head is received in the protective pocket.

31. (Original) The cranial orthosis for preventing positional plagiocephaly in infants as set forth in claim 29, wherein the rostral end portions are dimensioned to provide at least partial overlapping coverage over the fronto-parietal and temporal areas of the infant when the infant's head is received in the pocket.

32. (Original) The cranial orthosis for preventing positional plagiocephaly in infants as set forth in claim 29, including a band of soft flexible material connected to the rostral end portions and bridging across the forehead of the infant when the infant's head is received in the pocket.

33. (Original) The cranial orthosis for preventing positional plagiocephaly in infants as set forth in claim 32, wherein the band comprises a layer of woven fabric material.

34. (Original) The cranial orthosis for preventing positional plagiocephaly in infants as set forth in claim 32, wherein the band comprises a layer of open cell foam material.

35. (Original) The cranial orthosis for preventing positional plagiocephaly in infants as set forth in claim 24 wherein the molded appliance is generally U-shaped in cross section and has bilateral symmetry.

36. (Original) The cranial orthosis for preventing positional plagiocephaly in infants as set forth in claim 24, wherein the molded appliance comprises a unitary molding formed of a plastic resin material.

37. (Original) The cranial orthosis for preventing positional plagiocephaly in infants as set forth in claim 24, wherein the molded appliance comprises a headband formed of a plastic resin material.

38. (Original) The cranial orthosis for preventing positional plagiocephaly in infants as set forth in claim 24, wherein the molded appliance comprises a helmet formed of a plastic resin material.

39. (Original) The cranial orthosis for preventing positional plagiocephaly in infants as set forth in claim 24, including a layer of soft, flexible material covering the conformed interior surface of the molded appliance.

40. (Original) The cranial orthosis for preventing positional plagiocephaly in infants as set forth in claim 24, including two or more layers of soft, flexible material releasably disposed in overlapping nested relation and covering the conformed interior surface of the appliance, whereby the layers can be removed one at a time to accommodate head growth.

41. (Original) The cranial orthosis for preventing positional plagiocephaly in infants as set forth in claim 40, wherein the layers are provided in different colors that correspond with different fronto-occipital circumference increments.

42. (Currently amended) A method for preventing postural plagiocephaly in a human infant having a cranium that is substantially normal in size and curvature for its age and gender, comprising the steps:

(a) providing a protective appliance in the form of a shell, headband or helmet having an interior surface that is operable to accommodate infant head growth and contoured to conform to the head shape of a healthy human infant of the same age and gender, thereby defining a pocket for receiving the head of the infant having a soft developing area to be protected, wherein the pocket is sized to provide a close, non-interfering fit about the infant's head when the appliance is worn by the infant in a protective position in which the contoured interior surface is disposed in facing relation to the soft developing area to be protected; and

(b) causing the infant to wear the protective appliance while resting on a sleep surface in the supine position.

43. (Original) The method for preventing postural plagiocephaly in infants as set forth in claim 42, including the steps:

lining the interior surface of the protective headband with one or more layers of soft, spongy material or fabric material; and

removing one or more of the layers to accommodate growth of the infant's head.

44. (Original) The method for preventing postural plagiocephaly in infants as set forth in claim 42, including the steps:

- (a) providing an inventory of the protective appliances, each of the appliances having a pocket conforming substantially in size and shape to the cranium of a healthy human infant of given age and gender, the inventory comprising a plurality of the protective appliances of various cavity sizes that are indexed according to age, gender and average fronto-occipital circumference values tabulated for the general infant population;
- (b) measuring the fronto-occipital circumference of the infant's head; and
- (c) selecting for the infant's treatment a protective appliance from the inventory that most closely matches the infant's head size, age and gender.

45. (Currently amended) A method for preventing postural plagiocephaly in infants having a soft developing area to be protected, comprising the steps:

providing a cranial orthosis having an interior surface that is operable to accommodate infant head growth and conformed to the shape of a human infant head having normal curvature and symmetry;

fitting the cranial orthosis about head of an infant with a portion of the conformed interior surface facing the soft developing area to be protected; and

supporting the soft developing area of the infant's head on the facing portion of the conformed interior surface while the infant is resting on a sleep surface in the supine position.

46. (Original) The method for preventing postural plagiocephaly in infants as set forth in claim 45, including the step:

allowing the infant's head weight forces to spread substantially uniformly across the facing portion of the conformed interior surface that is engaged by the soft developing areas while the infant is in the supine position.

47. (Original) The method for preventing postural plagiocephaly in infants as set forth in claim 45, wherein the conformed interior surface forms the boundary of a protective pocket in which the infant's head is received, including the



step of sizing the protective pocket to provide a close, non-interfering fit of the conformed interior surface adjacent to the developing head area.

48. (Original) The method for preventing postural plagiocephaly in infants as set forth in claim 45, wherein the conformed interior surface forms the boundary of a protective pocket in which the infant's head is received, including the step of sizing the protective pocket to provide nesting engagement of the developing head area against the conformed interior surface.

49. (Original) The method for preventing postural plagiocephaly in infants as set forth in claim 45, wherein the conformed interior surface forms the boundary of a protective pocket in which the infant's head is received, including the step of sizing the protective pocket to provide a close, non-compressive fit of the conformed interior surface about the developing head area.

50. (Original) The method for preventing postural plagiocephaly in infants as set forth in claim 45, wherein the conformed interior surface forms the boundary of a protective pocket in which the infant's head is received, including the step of sizing the protective pocket to provide a slightly oversized fit relative to the head of an infant to be protected without imposing binding engagement of the orthosis against the developing area of the infant's head.